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March 20, 2024

VIA CM/ECF

The Honorable Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower
18th Floor
Philadelphia, Pennsylvania 19103

RE: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-02875 (D.N.J.)

Dear Judge Vanaskie:

I am writing in response to plaintiffs' March 19, 2025 letter regarding ZHP's production of certificates of analysis ("COAs") and material safety data sheets ("MSDSs"), as well as the parties' ongoing discussions related to document retention policies.

As an initial matter, ZHP believes that it has fully complied with the Court's March 12 Order, which required it to "produce the at-issue [COAs] and [MSDSs]" by March 17 and to "file a status report concerning ZHP document retention policies and its production of [COAs]" by March 18. (ECF 2989.)

First, with respect to the production of COAs and MSDSs, ZHP conducted appropriate searches and produced the documents it located on March 17, consistent with the Court's March 12 Order. ZHP did not locate any at-issue COAs that predated 2015.

As counsel explained at the March 3, 2025 case management conference, this is not surprising, as ZHP receives thousands of COAs from its raw material suppliers, which it maintains in hard copy in a manner consistent with U.S. and other regulatory requirements as well as its internal procedures. For example, 21 C.F.R. § 211.180 requires the retention of "any production, control, or distribution record" that is "specifically associated with a batch of a drug product" for one year after the expiration of the batch, and ZHP's standard operating procedures (e.g., ZHP01525948) incorporate regulatory and other requirements in setting forth retention periods for records related to API manufacturing.

Likewise, as discussed with plaintiffs during the parties' meet-and-confer conversations on these issues, it is not surprising that ZHP was only able to identify one MSDS for each substance at issue. MSDSs contain information about potential work place hazards associated with a particular chemical or material and instructions for safe handling, and they are typically provided on a periodic basis by a supplier (often only once, when a supplier is initially contracted to provide the material, with a new MSDS provided only if there is a material change in information). As a result, ZHP does not believe that it would have received many versions of the applicable MSDSs.

Second, ZHP also complied with the Court's order that ZHP provide a status report regarding the production and the ongoing discussions between the parties about ZHP's document retention policies. ZHP provided an update to the Court on March 17, 2025, explaining that it had completed its production on March 17, 2025. ZHP also noted that it had not yet heard back from plaintiffs with regard to the draft stipulation regarding

document retention that ZHP sent to plaintiffs on March 7, 2025. That proposed stipulation relates to the retention of ***custodial*** documents and was raised in the context of plaintiffs' request for a deposition of Jinsheng Lin, ***not*** in connection with the COAs. In their letter to the Court yesterday, however, plaintiffs asserted for the first time that they are also seeking document retention policies related to the retention of ***COAs***. The Court's March 12 Order did not require production of these materials. In any event, ZHP produced retention policies for documents like COAs more than four years ago (*see, e.g.*, ZHP01525948) and pointed to these very documents again in early December 2024 (*see* Exhibit A (December 3, 2024 Email from M. Hansen to C. Geddis and A. Slater)). And even if they had not, as Judge Bumb noted during the last case management conference when other discovery issues were raised after the passage of so much time, it is "just astounding" that these issues are being raise "this late in the game," years after the close of discovery and months away from a bellwether trial. (3/3/2025 CMC Tr. 40:22-23 (ECF 2992).)

Plaintiffs make another new discovery request, asking ZHP to produce "Chinese standards" for DMF, triethylamine, and triethylamine hydrochloride from January 1, 2010 to July 13, 2018. We assume this request relates to the Chemical Industry Standards which set forth, among other things, specifications with which all chemicals sold in the People's Republic of China must comply. It is our understanding that such specifications are publicly available, but we are working to confirm this—and, if they are not, we will work with plaintiffs to address this request.

Finally, plaintiffs also suggest that the COAs for dimethylformamide ("DMF") produced by ZHP earlier this week are materially different than those in the sample production of COAs made in December. (ECF 2995.) This is incorrect. The sample COAs previously produced to plaintiffs contain documents in the same format as those in the current production—i.e., some refer to "Alkalinity (calculated as dimethylamine) w/%" while others refer to "Alkalinity %." In addition, while the newly produced COAs demonstrate that there is variation in the alkalinity found in the DMF batches used by ZHP, this variation was also reflected in the COA documents previously produced to plaintiffs. For example, one version of a DMF COA notes 0.0005 % alkalinity (ZHP03121853) while another version of a COA notes 0.0000 % alkalinity (ZHP03121839). In short, the COAs produced this week are consistent with the exemplars plaintiffs have had since December—and, in any event, regardless of the parties' respective interpretations, plaintiffs now have all the copies available to ZHP.

In short, while ZHP is certainly willing to continue to meet and confer with plaintiffs to address questions they may have with respect to the materials produced, there can be no question that ZHP complied in good faith with this Court's March 12 Order.

Very truly yours,

Richard T. Bernardo